

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Dkt. No. 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

All Actions

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM IN RESPONSE
TO PREMIER'S REPLY TO THE PLAINTIFF'S PSC'S CROSS-MOTION TO
AMEND CMO #9 [ECF 1874] AND IN OPPOSITION TO BOX HILL
DEFENDANTS' MOTION FOR STAY OR TO EXTEND THE COMMON ISSUE
FACT DISCOVERY DEADLINE TO APRIL 1, 2016 AND OPPOSITION TO
PSC'S CROSS MOTION TO AMEND MDL ORDER NO. 9 [ECF NO. 1889]**

The Premier and Box Hill Defendants seek to take advantage of the motion practice engaged in by the NECC and Affiliated Defendants to unnecessarily delay discovery of their clients. Since the PSC began to meet and confer on an extension of the discovery deadline, we have already seen the postponement of two Premier related depositions and have yet to receive a single document from Box Hill in response to the Plaintiff's First Request for Production of Documents. Their lackadaisical approach to the discovery process set forth by this Court has become obvious, establishing the need for clear deadlines and a trial date.

A. The PSC Does Not Object to a Brief Extension of the Deadline for Common Discovery

The deadline for Common Issue Fact Discovery was set forth by this Court last year, on September 18, 2014.¹ However, in the spirit of compromise, the PSC does not object to a 45 day extension of the deadline as to Common Fact Discovery as to Settling

¹ See *In Re: New England Compounding Pharmacy Cases Litigation*, MDL No. 13-02419-RWZ, Dkt. No. 1425 (September 18, 2014).

Defendants.² Furthermore, in an effort at accommodation, the PSC has generously offered to extend the Common Issue Discovery deadline as to the Premier Defendants to November 15, 2015 and as to the Box Hill Defendants until January 2016, which is far more time than should be necessary to conduct less than a dozen clinic specific depositions each.

B. The Premier and Box Hill Defendants' Need for an Extension is a Result of Their Failure to Timely Conduct Discovery

The Premier and Box Hill Defendants did not begin requesting discovery from NECC, the Affiliated Defendants, the National Defendants and/or third parties until March of 2015, a full six months AFTER the Court opened Common Issue Fact discovery. Had the Premier and Box Hill Defendants diligently pursued the discovery it now seeks, many of the pending motions would have been decided and discovery complete. Thus, Premier and Box Hill Defendants' professed need for an extension is a result of their failure to promptly issue and respond to discovery, and a lengthier extension beyond the PSC's proposal is not necessary.

Additionally, common discovery has been ongoing, as hundreds of thousands of pages of documents have been produced and depositions of multiple settling and third party defendants have been underway, scheduled or unopposed, including Liberty Industries, Inc., Scientific Air Analysis, Inc., Victory Mechanical Services, Inc., Victory Heating & Air Conditioning Co., Inc., Microbiology Research Associates, Inc., Brigham and Women's Hospital, the Massachusetts Board of Registration in Pharmacy, Unifirst Corporation, UniClean Cleanroom Services, and other clinic related management

² The PSC has updated its Proposed Order for the Motion to Amend CMO No. 9 to reflect the 45 day extension, attached as Exhibit A.

companies. And any arguments related to the importance of a deposition of the FDA (which has taken the position it will not appear for deposition until after the Barry Cadden criminal trial) related to the FDA's "regulation" of NECC is without merit. As the Defendants well know, the FDA could not regulate NECC or any other compounding pharmacies in 2012.³ In 2001, the Ninth Circuit held that § 503A of the Food, Drug, and Cosmetic Act, which had been enacted in 1997 to give the FDA regulatory power over compounding pharmacies, was unconstitutional in its entirety.⁴ Surely this MDL proceeding cannot be held hostage for this deposition or the deposition of the insiders, particularly where extensive documentary discovery has been produced and where there are alternative methods to obtaining discovery that does not prejudice the plaintiffs through undue and unnecessary delay.

C. Any Extension set by the Court for the Close of Common Discovery Should not Affect the Timeframes Proposed in Amended CMO No. 9B

If the Court is inclined to grant an extension of the common discovery deadlines, timeframes proposed in CMO No. 9, as well as the PSC's Motion to Amend CMO No. 9 should apply and not be drawn out. Considering that the St. Thomas Defendants believe that their discovery as to NECC, the Affiliated Defendants, the National Defendants and/or third parties will be completed by September, it is difficult to understand why the Premier and Box Hill Defendants believe they require longer.

³ See Galston SK. *Federal and state role in pharmacy compounding and reconstitution: exploring the right mix to protect patients. Hearing on Oversight Before the Senate Committee on Health, Education, Labor, and Pensions, 108th Cong. October 23, 2003.*

<http://www.fda.gov/NewsEvents/Testimony/ucm115010.htm> Accessed May 27, 2015. (The "FDA has historically exercised its enforcement discretion in a manner that defers to the states, as the regulators of the practice of pharmacy, to serve as the primary regulators of the practice of pharmacy compounding.")

⁴ See *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1098 (9th Cir. 2001) *aff'd sub nom. Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002).

Notably, the discovery extensions proposed by the PSC and Premier are not that far off. Where the schedules diverge is where the PSC follows the schedule contemplated by the Court in CMO No. 9 and mirrors those dates with the extension, and the Premier Defendants do not. The PSC strongly believes a trial date of August 2016 against Premier Defendants, who themselves admit that they have been participating in this litigation for over two years, is more than reasonable.

On the other hand, the proposals for extension of discovery deadlines as to Box Hill Defendants and the PSC are worlds apart as are the proposed trial dates. Box Hill claims that the cases against it should be stayed given that all the cases against it are not yet currently pending and therefore, it does not know the universe of cases that it will face. First, this is untrue, and second, this is a fact of no consequence. Indeed, Box Hill admits that it has received 25 demands in addition to the 8 pending cases, clearly placing them in the category far above 5 or less cases and exceeding the number of cases against the Premier Defendants. Second, the PSC's proposed revised schedule contemplates common fact discovery of Box Hill and related witnesses going forward one time, now through January 2016. Even if a case is filed in September or early October, the PSC's position is that the discovery done of Box Hill and related witnesses will be done only once and no future filed plaintiffs may re-open discovery that has already been done, protecting Box Hill against any potential prejudice. The PSC's proposed schedule allows Box Hill approximately five months from that timeframe in which all cases should be filed against it to perform additional discovery and case specific bellwether discovery.

Conclusion

Lengthy extensions pushing trial dates well into 2017 will not further efficient and judicious resolution of these matters and will only prejudice the victims and continue to unnecessarily clog the Court's docket. The PSC recognizes, however, the realities of the various pending discovery-related motions necessitate a flexible approach. The PSC believes a reasonable extension is warranted, but it opposes a complete stay as it relates to Box Hill and an additional 8 month extension of discovery for Premier. Given the circumstances, the PSC proposes a 5 month extension for Premier and 7 month extension for Box Hill of all non-expired deadlines in CMO No. 9 and trial dates of August 2016 for Premier and October 2016 for Box Hill.

Dated: May 27, 2015

Respectfully submitted,

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Kimberly A. Dougherty, hereby certify that I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: May 27, 2015

/s/ Kimberly A. Dougherty
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